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10/528,930	09/06/2005	Lone Andersen	0114229/0556836	6400
26874	7590	05/26/2009	EXAMINER	
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			ART UNIT	PAPER NUMBER
			1794	
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			05/26/2009	ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patents@fbtlaw.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/528,930	<b>Applicant(s)</b> ANDERSEN ET AL.	
	<b>Examiner</b> Nikki H. Dees	<b>Art Unit</b> 1794	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 13 March 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-20,23,24,26-43 and 45-64 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-20,23,24,26-43 and 45-64 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on March 13, 2009, has been entered.
2. Claims 1-20, 23, 24, 26-43, and 45-64 are currently pending in the Application.

### ***Claim Objections***

3. Claims 1, 6, 12, and 17 are objected to because of the following informalities: claims 1, 6, 12, and 17, claim a "group consisting of" only one member. If there is only one member claimed, it is not considered to be a group. Appropriate correction is required.
4. Claims 27, 29, and 37 objected to because of the following informalities: claims 27 and 29 lack a final punctuation mark. Claim 37, change "sterioside" to "stevioside". Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1, 3-5, 6, 9, 10, 17, and 19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

7. Claim 1 claims a chewing gum “substantially free” of non-biodegradable polymers. It is unclear how much, or how little, non-biodegradable polymer the chewing gum may contain to be considered “substantially free” of the non-biodegradable polymer.

8. Claims 3-5, 10, and 17 claim a “comonomer.” It is understood that the backbone of the polymer comprises at least two different monomers. However, it is unclear how this “comonomer” differs from the backbone monomer and why it is claimed as a comonomer instead of a second monomer. Appropriate correction is required without the addition of new matter.

9. Additionally, claims 4 and 5 refer to “the at least one backbone comonomer”. There is no antecedent basis in claim 1 for “the at least one backbone comonomer” of claims 4 and 5.

10. Claim 6 claims the at least two different monomers are lactone monomers. As the two monomers are different monomers, it is unclear all of the at least two monomers

Art Unit: 1794

both must be lactone monomers, or if only at least one of the monomers must be a lactone monomer.

11. Claim 9 to a monomer having a  $T_g$  below  $-40^{\circ}\text{C}$  is considered to be indefinite. As  $T_g$  is a commonly reported property of polymers, it is unclear if the claimed  $T_g$  is to be of the unpolymerized monomer, or a polymer consisting of the monomer. For purposes of examination, the claim will be interpreted as being the  $T_g$  of a polymer of the monomer.

12. Claim 17 is further indefinite as it is unclear what the "at least one monomer" is in reference to. It is unclear if applicant is limiting the "at least one backbone monomer," or if there is a third monomer present in the degradable polymer.

13. Claim 19 refers to the multifunctional initiator of claim 1. There is no antecedent basis in claim 1 for the multifunctional initiator.

### ***Claim Rejections - 35 USC § 102***

14. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

15. Claims 1-16, 23, 24, 26-41, 45-50, 55 and 57-64 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Goldberg et al (WO 01/47368) with evidence provided by Koleske et al. (Koleske, J.V., Lundberg, R.D. 1972. Lactone

Art Unit: 1794

Polymers. IV. Glass Transition Temperatures of Monomeric Lactones and Their Polymers. J. Polymer Sci. pp. 323-337).

16. Regarding claims 1-8, 10-16, and 58-64, Goldberg et al. disclose a chewing gum, free of non-biodegradable polymers (p. 17, ¶5), including a multifunctional polyol initiator (p. 17, ¶4) and two different monomers (p. 17, ¶1) forming the backbone of a biodegradable chewing gum polymer as claimed by applicant in the amounts as claimed by Applicants. Goldberg et al. teach carbonate monomers,  $\epsilon$ -caprolactone and  $\delta$ -valerolactone (pp. 11-12).

17. Regarding claim 9, the glass transition temperature is also within applicant's claimed range, as evidenced by Koleske et al. (Tables I and II).

18. Regarding claims 23 and 24, the monomers have molecular weights within Applicant's claimed ranges (p. 10 lines 1-4).

19. Regarding claims 26-32, Goldberg et al. teach flavoring agents in the chewing gum including essential oils and extracts (p. 7, ¶2). Specific examples teach flavoring agents (peppermint flavors) present in the chewing gum at 1.8 wt%, anticipating Applicant's claimed range (Example 48, Chewing Gum Formulation).

20. Regarding claims 33-38, Goldberg et al. teach sweeteners for use in their chewing gum including bulk sweeteners (p. 6 lines 29-30; p. 7 lines 11-14). Example 48, Chewing Gum Formulation teaches the presence of bulk sweeteners (sorbitol and mannitol) at about 55 wt %. The high intensity sweetener aspartame is present in an amount of about 1 wt%, anticipating applicant's claimed ranges.

Art Unit: 1794

21. Regarding claims 39-41, Goldberg et al. teach softeners for inclusion in their chewing gum. Softeners taught include palmitic acid and stearic acid, among others. The softeners are generally present in amounts up to 18 % by weight of the chewing gum base, indicating they would inherently be present in Applicant's claimed amount in the chewing gum product (p. 5).
22. Regarding claims 45 and 46, Goldberg et al. teach fillers for inclusion in their chewing gum products at up to 60 % by weight of the chewing gum base (p. 5 ¶2-p. 6 lines 1-2).
23. Regarding claim 47, Goldberg et al. teach coloring agents for inclusion in their chewing gum product (p. 6 line 4).
24. Regarding claims 48-50 and 55, the chewing gum in Goldberg et al. may be coated with a syrup, which results in a hard or soft coating (p. 9 ¶1-2).
25. Regarding claims 57, 61, and 62, Goldberg et al. teach conventional chewing gum polymers and resins for use in their invention (pp. 4-5).

### ***Claim Rejections - 35 USC § 103***

26. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Art Unit: 1794

27. Claims 17-20, are rejected under 35 U.S.C. 103(a) as being unpatentable over Goldberg et al. (WO 01/47368).

28. Goldberg et al. teach a chewing gum product as detailed above.

29. Goldberg et al. teach that the different monomers may be present in their invention at 51-99 wt % of the first monomer (p. 13 lines 9-14) and 0.1 to 40 wt % of the second monomer (p. 16 lines 17-24). Goldberg et al. also teach that “the optimal level of the second monomer will depend on the specific structure of the second monomer and can be determined by those skilled in the art.” They further state that one or more monomers from the first and second groups may be present in the polymers of their invention (p. 17 lines 1-3).

30. Goldberg et al. are silent as to the amounts of the monomers as required by claim 17. They are also silent as to the amount of initiator required in their invention and the changes that result in the adjustment of the amount of the initiator.

31. Regarding claim 17, as Goldberg et al. provide ranges overlapping those claimed by Applicant for the amount of monomers to be present in the polymer of their invention, as well as teach that the artisan would have been able to determine the amount of monomers to incorporate depending on the final polymer desired, the arrival at the ranges of polymers as claimed is considered to have required no more than routine experimentation based on the teachings of the prior art.

32. Similarly, regarding claims 18-20, as Goldberg et al. provide for the use of initiators as claimed, one of ordinary skill would have been able to determine the appropriate initiator, as well as the amount of initiator, to utilize in the polymer in order to



Art Unit: 1794

result in a biodegradable polymer having the desired characteristics. The adjustment of the initiator would additionally result in the desired rheological properties of the chewing gum polymer as claimed. The determination of the type, amount, and functional number of the initiator would have been well within the abilities of one of ordinary skill in the art at the time the invention was made.

33. Claims 42 and 43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goldberg et al. (WO 01/47368) in view of Li et al (6,153,231).

34. Goldberg et al. teach a chewing gum product as detailed above.

35. Goldberg et al. are silent as to the inclusion of active ingredients in the chewing gum product.

36. Li teaches active ingredients for inclusion in chewing gum products (col. 7, lines 60-61).

37. One of ordinary skill in the art at the time the invention was made wishing to provide a chewing gum comprising active agents would have found it obvious to include a pharmaceutical agent in the chewing gum of Goldberg et al since it is conventional to include such an active ingredient in chewing gum, as evidenced by Li et al.

38. Claims 51-54 and 56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goldberg et al. (WO 01/47368) in view of Meyers (5,433,960).

39. Goldberg et al. teach a chewing gum product as detailed above.

Art Unit: 1794

40. Goldberg et al. are silent as to the chewing gum product comprising coating components and film forming agents as required by claims 51-54 and 56.

41. Regarding claim 51, Meyers teaches the coating of the chewing gum with low calorie bulking agents and polyols. One of ordinary skill would have recognized that the claimed polyols are commonly used as coating agents in the chewing gum art.

42. Regarding claims 52-54 and 56, Meyers teaches an outer coating of a chewing gum comprising sugar-free sweeteners and flavors (col. 11 lines 11-46).

43. One of ordinary skill in the art at the time the invention was made wishing to provide a chewing gum with a sweetened and/or flavored coating would have found it obvious to coat the chewing gum in Goldberg et al. with a coating as claimed by applicant in order to provide storage stability to the chewing gum since it is well known to coat chewing gum products with each of applicant's claimed coating materials in order to achieve this objective, as evidenced by Meyers.

### ***Double Patenting***

44. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422

Art Unit: 1794

F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

45. Claims 1-20, 23, 24, 26-43, and 45-64 are also provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-62 of copending Application No. 10/472,122; claims 1-66 of copending Application No. 10/528,926; claims 1-7, 14-26, 28-31, and 33-57 of copending Application No. 10/528,927; claims 1-20, 22, 23, 25, 26, 28-30, and 36-42 of copending Application No. 10/529,133; claims 1, 3-7, and 9-55 of copending Application No. 10/529,137; and claims 1, 10, 11, 13-18, 24-26, 28-39, and 41-54 of copending Application No. 11/088,109 each set of claims being in view of Goldberg et al. Although the conflicting claims are not identical, the use of multifunctional polyol initiator in preparing the biodegradable chewing gum polymers claimed in each of the conflicting applications would have been obvious to one of ordinary skill as the use of multifunctional polyol initiators is well known in making claimed biodegradable polymers, as evidenced by Goldberg et al.

This is a provisional obviousness-type double patenting rejection.

### ***Response to Arguments***

46. Applicant's arguments filed March 13, 2009, have been fully considered but they are not persuasive.

47. Applicant argues that the teachings of Goldberg no longer anticipate claim 1 wherein the chewing gum is substantially free of non-biodegradable polymers (Remarks, pp. 13-14 and p. 17).

48. Applicant is directed to Goldberg at p. 17 5<sup>th</sup> paragraph where it is stated that the gum bases "typically comprise from about 1 to 99 wt%... of the copolymers of the present invention." The teaching of about 99 wt% of degradable polymers of Goldberg in the chewing gum base is considered to meet Applicant's amended claim to a chewing gum "substantially free of non-biodegradable polymers."

49. The examiner is unclear what point Applicant is making with the remarks on p. 15, in particular where Applicant states Goldberg does not point out directions to follow to obtain polymers suitable for chewing gum.

50. As Applicants have pointed out, the title of Goldberg's publication is "Degradable polymers for chewing gum bases." The title would indicate to one of ordinary skill that the polymers disclosed within would be suitable for use in chewing gum bases.

51. Applicant goes on to argue (Remarks, p. 16) that the number of possible polymers taught by Goldberg is too vast for one of ordinary skill to have arrived at the claimed invention.

52. In response, it is noted that "when the species is clearly named, the species claim is anticipated no matter how many other species are additionally named. Ex parte A, 17 USPQ2d 1716 (Bd. Pat. App. & Inter. 1990) (The claimed compound was named

in a reference which also disclosed 45 other compounds. The Board held that the comprehensiveness of the listing did not negate the fact that the compound claimed was specifically taught. The Board compared the facts to the situation in which the compound was found in the Merck Index, saying that "the tenth edition of the Merck Index lists ten thousand compounds. In our view, each and every one of those compounds is described' as that term is used in 35 U.S.C. § 102(a), in that publication.") MPEP § 2131.02.

53. As Goldberg teaches the specific monomers for use in biodegradable chewing gum polymers, as is claimed by Applicants, the teachings of Goldberg are considered to anticipate Applicant's claims as detailed above.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nikki H. Dees whose telephone number is (571) 270-3435. The examiner can normally be reached on Monday-Friday from 7:30 AM to 5:00 PM (second Friday off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Keith Hendricks, can be reached on (571) 272-1401. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1794

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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